CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-559

MICROBIOLOGY REVIEW

Product Quality Microbiology Review
Review for HFD-510

29 January 2003

NDA: 21-559

Drug Product Name
Proprietary: Infuvite® Adult — (pharmacy bulk package)
Non-proprietary: vitamins for infusion
Drug Product Classification: Multidose Injectable

Review Number: 1

Subject of this Review
Submission Date: 14 August 2002
Receipt Date: 16 August 2002
Consult Date: 21 August 2002
Date Assigned for Review: 27 September 2002

Applicant/Sponsor
Name: Sabex Pharmaceutical Products
Address: 145 Jules-Leger, Boucherville, QC, Canada
Representative: Leonor Ferreira
Telephone: (450)641-4903 ext. 2161

Name of Reviewer: Paul Stinavage

Conclusion: The application is recommended for approval on the basis of sterility assurance.

Product Quality Microbiology Data Sheet

A. 1. **TYPE OF SUPPLEMENT:** Prior Approval

2. **SUPPLEMENT PROVIDES FOR:** Addition of a pharmacy bulk package.

3. **MANUFACTURING SITES:** Boucherville (Quebec), Canada

4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** Intravenous

5. **METHOD(S) OF STERILIZATION:** ———

6. **PHARMACOLOGICAL CATEGORY:** The product is indicated as a daily multivitamin supplement for adults and children aged 11 and older receiving parenteral nutrition.

B. **SUPPORTING/RELATED DOCUMENTS:** NDA 21-163, NDA 21-265, DMF

C. **REMARKS:** The product will be manufactured by:

Sabex
145 Jules-Leger Street
Boucherville, QC, Canada
J4B7K8

The supplement references NDA 21-163 for Infuvite Adult which was approved 13 June 2001. The applicant states that the subject product contains the same active ingredients as Infuvite Adult and is manufactured using identical processes.

This review was originally issued to NDA 21-163/SLR-006 dated 07 October 2002 because the reviewer was unaware that the NDA number had changed as a result it involving a pharmacy bulk package. That submission (NDA 21-163/SLR-006) has been deleted from the DFS system. The review (NDA 21-559 dated 29 January 2003) is unchanged from the original and is being reissued to the correct DFS file.

filename: h21559.doc

Executive Summary

I. Recommendations

A. Recommendation on Approvability – The application is recommended for approval on the basis of sterility assurance.

B. Recommendations on Phase 4 Commitments and/or Agreements, if Approvable -

II. Summary of Microbiology Assessments

A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology –

B. Brief Description of Microbiology Deficiencies – none

III. Administrative

A. Reviewer's Signature _____

B. Endorsement Block
P. Stinavage
P.H. Cooney

C. CC Block
cc:
Original NDA 21-163
HFD-510/Division File/NDA 21-163/S. McCort

1 Page(s) Withheld

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Paul Stinavage
1/29/03 06:25:16 AM
MICROBIOLOGIST
Reissue of review for NDA 21-163/SLR-006 as a result of change in NDA number to NDA 21-559.

Peter Cooney
1/29/03 08:20:15 AM
MICROBIOLOGIST